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Mark Deem

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EXAMINER

EREZO, DARWIN P

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/791,469	Applicant(s) DEEM ET AL.	
	Examiner Darwin P. Erez	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-16, 18-24, 33-40 and 55-84 is/are pending in the application.
- 4a) Of the above claim(s) 74-84 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-16, 18-24, 33-40 and 55-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is in response to the applicant's communication filed on 2/22/10.

Election/Restrictions

2. Newly submitted claims 74-84 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claims 74-78: The originally filed claims and the invention of claims 74-78 are directed towards patentably distinct species. The originally filed claims recite that the leg members are removably coupled to the main graft while the invention of claims 74-78 now recite that the leg members are permanently coupled to the main graft. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record (applicant's arguments in page of the remarks filed on 2/22/10). There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Claims 79-84: The originally filed claims and claims 79-84 are related as combination and subcombination. Inventions in this relationship are distinct if it can be

shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the originally filed claims do not require a cylinder having a middle portion comprising both self-expanding members and a balloon-expandable members. The subcombination has separate utility such as a stent support without a graft.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 74-84 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
6. Claims 1, 10-16, 18-24, 33-36 and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,129,756 to Kugler et al. in view of US 2003/0236567 to Elliot, in view of US 2004/0193254 to Greenberg et al., and in further US 6,409,750 to Hyodoh, et al.

Kugler discloses a stent-graft device comprising at least one self-expandable member **10** (col. 10, ll. 48-49); at least one tubular graft member **40,41** coupled to the stent member, the tubular graft member having leg members **20,30** and coupled with a self-expandable iliac stent (shown in Fig. 2); wherein the leg members are fully capable of being removed from the main graft members; wherein the self-expandable stent member **10** has a proximal portion that is not attached to the graft member and acts as an anchoring member at any location along vascular system, including a location superior to the renal arteries branching from the abdominal aorta or a location inferior to the renal arteries branching from the abdominal aorta; wherein the stent is formed from

a wire (thus joining the unattached portion of the stent to the attached portion of the stent).

Kugler is silent with regards to the device comprising a skirt graft member coupled to the stent member and the graft member, wherein the skirt member is configured to contact the inner wall of an aortic aneurysm; and wherein the tubular graft member, once deployed, comprises a sinusoidal leg member having a shape memory material.

However, Elliot discloses a similar stent-graft device for treating aneurysm, wherein the device has a skirt **18** that is configured to contact the inner wall of an aneurysm. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kugler to have a skirt portion as disclosed by Elliot because the skirt provides a seal between the aneurysm and the device.

With regards to a sinusoidal leg member, it is noted that this configuration is well known in the art. For example, Greenberg discloses a branched stent device similar to that of Kugler, wherein the device comprises a sinusoidal leg member (see Figs. 8a-8d). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kugler to also have a sinusoidal leg member since the shape is taught to be well known in the art, as disclosed by Greenberg.

It would also be obvious to modify both leg members to be sinusoidal instead of just one since it has been held that mere duplication of the essential working parts of a

device involves only routine skill in the art. *In re Harza*, 274 F.2d, 669, 124 USPQ 378 (CCPA 1960). Note that having two sinusoidal leg members would allow said leg members to intertwine.

With regards to the sinusoidal members comprising shape memory material, it is noted that forming stents from shape memory material is well known in the art, as disclosed by Hyodoh in col. 20, 49-66. Therefore, one of ordinary skill in the art would have found it obvious to use shape memory material since the use of said material is well known in the art, and since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). Modifying a sinusoidal member to have a shape memory material will inherently bias the leg member to the sinusoidal configuration (inherent in shape memory material).

7. Claims 2-7, 37, 55-58 and 60-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kugler et al. in view of Elliot; Greenberg et al. and Hyodoh, as applied to the claims above, and in further view of US 6,168,621 to Vrba.

The modified device of Kugler discloses all the limitations of the claims except for the stent member comprising both a self-expanding stent member and a balloon-expandable stent member. However, Vrba discloses a stent having both a self-expanding stent member and a balloon expandable stent member. This configuration is provided to allow immediate expansion of the stent member upon release, which will aid in placement of the stent during release but prior to using a balloon (col. 2, lines 4-12).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the stent member of Kugler to include both self-expanding and balloon-expandable stent members because it would allow the stent member to expand immediately upon release to position the stent in the right location prior to the expansion of a balloon, which would fully expand the entire stent member.

Vrba further discloses that the self-expanding stent members and the balloon-expanding stent members can be arranged in alternating sequence (col. 2, lines 50-55); wherein the stent member is made of nitinol (col. 2, line 7).

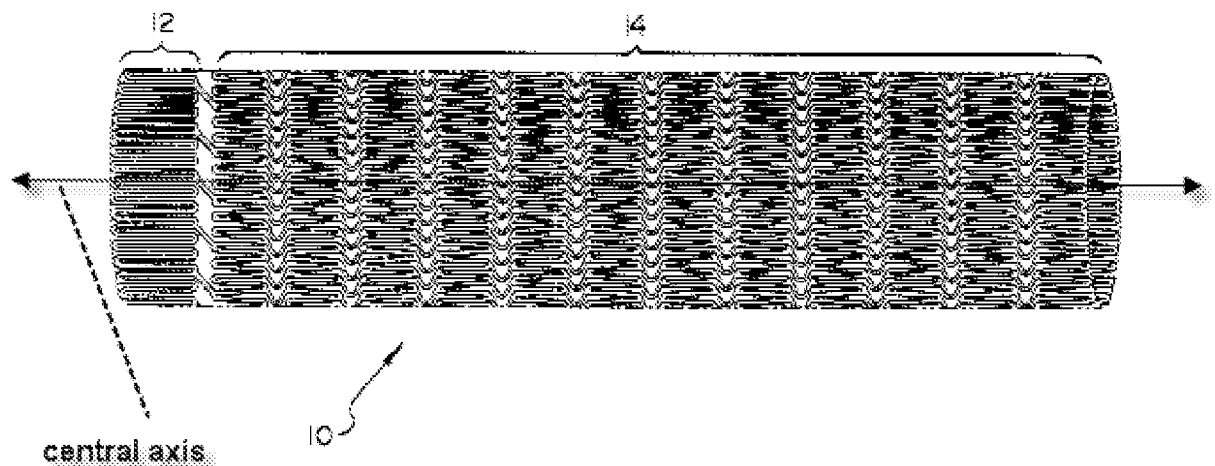
Vrba is silent with regards to the stent member being formed from stainless steel or to how the self-expanding stent members or the balloon-expanding stent members are connected to each other. However, the examiner takes Official notice that the use of stainless steel in medical devices, especially stents, are extremely well-known, and that connecting stent portions via welding, adhesive, soldering are also well-known in the art (as evidenced by US 5,843,176; col. 3, lines 49-57). Therefore, such modifications would be obvious to one of ordinary skill in the art. It is further noted that the common knowledge or well-known in the art statement is taken to be admitted prior art because the applicant failed to traverse the examiner's assertion of official notice.

Note that Vrba discloses a device that is formed to be a cylinder (see Fig. 6, the length of the device is cylindrical), wherein the cylinder is formed of alternating self-expanding members and balloon expandable members; wherein the entire length of the device is made of the expandable members (including the middle portion).

Though Vrba discloses the middle portion to be comprised of balloon-expandable members, it is noted that one of ordinary skill in the art would have found it obvious to rearrange the members to have the self-expanding members be located in the middle portion since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950). Note that the balloon expandable members is fully capable of being expanded to a larger diameter than the self-expanding members since the diameter of the balloon expandable members would merely be dependent upon the inflation size of the balloon.

It is further noted that the arrangement taught by Vrba is disclosed to be "laminated" together since they are "composed of layers firmly united materials" (as defined by Merriam-Webster online dictionary: www.m-w.com). Note that the applicant's specification does not clearly teach how the portions are laminated together.

With regards to the newly added limitation of claim 64, the examiner views the self-expandable and balloon expandable members of Vrba to be "radially laminated" by using the broadest reasonable interpretation afforded to the term "radially", which is "divergence from a center" or even "developing uniformly around a central axis" (see www.m-w.com for definition). As seen below, Vrba discloses a central axis with alternating self-expandable and balloon expandable members. Note that the applicant did not define how these members extend radially relative to the axis of the stent member.



8. Claims 8 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kugler et al. in view of Elliot, Greenberg et al., Hyodoh et al., and Vrba, as applied to the rejections above, and in further view of US 6,945,994 to Austin et al.

The modified device of Kugler discloses all the limitation of the claim except for the stent member having diamond-shaped members. However, Austin discloses a similar type of stent as Vrba, wherein the stent has both self-expanding and balloon-expandable stent members, and wherein the stent can have diamond-shaped, rectangular or even square patterns (col. 5, line 62). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the device of Kugler to include diamond-shaped stent members because Austin discloses that it is well known in the art for stents to have various shapes, including diamond-shapes.

Response to Arguments

9. Applicant's arguments with respect to claims 1, 10-16, 18-24, 33-36 and 38-40 have been considered but are moot in view of the new ground(s) of rejection.

10. Applicant's arguments regarding claim 55 have been fully considered but they are not persuasive. The applicant argued that Vrba fails to teach "a plurality of expandable members coupled together circumferentially to form a cylinder, where some of the expandable members comprise self-expandable material and balloon expandable material. However, this is not found persuasive as the claim limitation is not as narrow as argued by the applicant. The claim originally requires expandable members being coupled together circumferentially. Vrba clearly shows expandable members being coupled together circumferentially to form a cylinder. This portion of the claim does not require alternating self-expandable and balloon expandable members forming a cylinder. Instead, it only requires any expandable members forming a cylinder. The second portion of the limitation "where some of the expandable members comprise self-expandable material and balloon expandable material" describes what the expandable members are formed from, but again does not state alternating self-expandable and balloon expandable members forming a cylinder. Thus, the self-expandable members and balloon expandable members can be arranged axially and still cover the claim limitations.

11. With regards to newly added limitation for claim 64, see the updated rejections above.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who's telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3773

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erez/
Primary Examiner, Art Unit 3773